No. 17-1484

IN THE

Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION AND MEDICAL SOCIETY OF THE DISTRICT OF COLUMBIA IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*[1]

Amici are private, voluntary, nonprofit organizations of physicians dedicated to promoting the public welfare through the maintenance of the highest professional standards and the provision of quality healthcare.

Amicus the American Medical Association (AMA) is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty area and in every state.

Amicus the Medical Society of the District of Columbia (MSDC) is part of the federation of state, county, and specialty medical societies that constitute the AMA. With over 2,500 members, the MSDC is the largest medical organization representing metropolitan Washington physicians in the District. Since 1817, the MSDC has been supporting and advocating for patients, physicians, the medical profession, and the betterment of public health.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae* and their counsel, made any monetary contribution toward the preparation and submission of this brief. Pursuant to Rule 37.3, petitioners and respondents have consented to the filing of this *amici curiae* brief.

The AMA and MSDC join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

This case concerns the scope of HHS's obligation to engage in notice-and-comment rulemaking when adopting rules concerning provider reimbursement in the Medicare program. *See* 42 U.S.C. § 1395 *et seq.* As petitioner recognizes, the HHS action at issue here has a substantial financial impact on both hospitals and the public fisc. *See* Pet. 23; Pet. App. 4a. Yet HHS took the challenged action without prior notice to the medical community and without any opportunity for public comment. Through its retroactive effect, HHS's action created unfairness and disrupted settled financial expectations of healthcare providers. Moreover, because neither healthcare providers nor any other member of the public had an opportunity to weigh in, the rule was not informed by the practical insights that stakeholders can provide, or the policy concerns of all those throughout the nation who are affected by Medicare spending.

Although the physician members of the AMA and MSDC are not subject to this particular rule, they are substantially affected by other HHS rules and practices concerning Medicare reimbursements of physicians. When HHS engages in notice-and-comment processes concerning Medicare reimbursements for physicians, *amici* are consistent and active participants, who have successfully prevailed on HHS to modify its regulatory policy. The AMA and the MSDC thus have a strong interest in

ensuring that HHS's rulemaking regarding Medicare reimbursement is conducted in a fair, transparent, and fully informed way. Moreover, the medical associations can offer real-world knowledge of the conditions and circumstances of providing healthcare pursuant to Medicare regulations, and participating in the Medicare regulatory process, that will be useful to the Court's analysis.

SUMMARY OF ARGUMENT

Medicare pays for 20 percent of healthcare in the United States.[2] Medicare benefits paid in Fiscal Year 2017 amounted to nearly $700 billion, and Medicare payments to physicians in Calendar Year 2016 exceeded $100 billion.[3] For physicians, Medicare represents an important source of income: In 2016, among physicians other than pediatricians, 96 percent reported that they saw at least some patients who are covered by Medicare—and 9.6 percent of all physicians reported that more than half of their patients were covered by Medicare.[4] Because of the major role that Medicare plays in paying for American healthcare, HHS's actions concerning Medicare reimbursements

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[2] *See* Ctrs. for Medicare & Medicaid Servs., *National Health Expenditures 2017 Highlights* 2, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf (last visited Dec. 18, 2018).

[3] *See* Ctrs. for Medicare & Medicaid Servs., *Fast Facts*, https://www.cms.gov/fastfacts/ (last updated Aug. 1, 2018).

[4] *See* Kurt D. Gillis, *Policy Research Perspectives: Physicians' Patient Mix—A Snapshot from the 2016 Benchmark Survey and Changes Associated with the ACA* 3 & n.4 (2017), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/health-policy/PRP-2017-physician-benchmark-survey-patient-mix.pdf.

have an outsized effect on physicians and other healthcare providers.

As this case illustrates, discrete changes in HHS's Medicare reimbursement actions can have enormous effects on providers. This case concerns the method HHS used to calculate the "Medicare fraction," which is used in determining the "disproportionate share hospital" payment that hospitals receive for the additional costs they incur in providing services to low-income patients. *See* Br. for Resp'ts 8-9. According to HHS's own estimation, how the Medicare fraction is calculated has a huge financial impact on both hospitals and the government—implicating between $3 and $4 billion in Medicare reimbursements over nine years. Pet. 23; *see also* Pet. App. 23a ("The financial impact on the hospitals of this seemingly minor detail is in the hundreds of millions of dollars.").

The dispute in this case centers on whether HHS was required under the Medicare statute—specifically, 42 U.S.C. § 1395hh(a)(2) or (a)(4)—to use notice-and-comment rulemaking in setting forth its method for calculating hospitals' Medicare fraction. The court of appeals held that notice-and-comment rulemaking was required, because (among other things) HHS's calculation method is a "rule, requirement, or other statement of policy" that changes a "substantive legal standard" governing "payment for services." Pet. App. 12a-14a (quoting § 1395hh(a)(2)).

HHS takes the position that "the challenged action here is not 'a rule, requirement, or other statement of policy,'" Br. for Pet'r 39 (quoting 42 U.S.C. § 1395hh(a)(2)), because it is said not to have any "'future effect,'" *id.* (quoting 5 U.S.C. § 551(4)). "To the contrary," HHS asserts, "the agency in theory would remain free to calculate the fractions in other years

(between 2004 and 2013, at least, when no binding regulation was in effect) based on a different nonbinding interpretation of the statute, if it chose." *Id.* at 39-40. Were the law otherwise, HHS says, it "would jeopardize the flexibility" that HHS declares to be "essential" to its administration of Medicare. *Id.* at 42. In HHS's words, "[t]he notice-and-comment process can be 'long and costly' and 'often requires many years and tens of thousands of person hours to complete,'" and requiring notice-and-comment would accordingly have a "disruptive effect" on the Medicare program. *Id.* (quoting Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-51 (2000)).

Amici do not here respond to HHS's statutory analysis, which is amply addressed by respondents. Nor do *amici* weigh in on the proper method of calculating the "Medicare fraction," which does not apply to reimbursements for physician services and thus does not directly affect *amici*'s member physicians.

Instead, *amici* write to respond to HHS's general statements regarding the costs and burdens of notice-and-comment rulemaking in the Medicare program. What HHS's brief does not recognize is that HHS's failure to adopt prospective, generally applicable rules—and its failure to permit the public to weigh in on how the agency administers Medicare through notice-and-comment—can impose substantial costs and burdens on the providers and beneficiaries who participate in the Medicare program. *Amici* write to inform the Court of the real-world implications that follow when HHS forgoes notice-and-comment procedures when changing its approach to Medicare reimbursements.

The many physicians and patients who rely on Medicare are entitled to clear and certain rules so they will know which services are covered and whether there are special requirements governing how those services are to be performed. Generally applicable, prescriptive regulations accomplish this—but informal decision-making does not.

Given the immense stakes of Medicare reimbursement, clarity and consistency are paramount. As this case well demonstrates, even "seemingly minor" modifications in reimbursement determinations give rise to extreme financial consequences for providers, and ultimately their patients. And the effect of changes in Medicare reimbursements does not just change the dollar amounts to which providers are entitled. After all, physicians can be held liable—including criminally liable—under the False Claims Act if they fail to follow the rules when submitting Medicare claims, so it is imperative that they be able to ascertain what those rules are.

Moreover, clarity and transparency in Medicare rulemaking is equally if not more important to the general public, including patients. The number of healthcare dollars available for Medicare is large, but it is not infinite. The public has a right to know and weigh in on how the money is spent. If HHS determines that treatment for one medical condition or procedure will be reimbursed, but another will not, the agency should articulate why. Patients' health is at stake—and HHS must be transparent in its decision-making process.

While HHS may find notice-and-comment rulemaking burdensome, the notice-and-comment process is not an "arbitrary hoop[] through which federal agencies must jump without reason." *Sprint*

Corp. v. FCC, 315 F.3d 369, 373 (D.C. Cir. 2003). Instead, "[t]he essential purpose of according . . . notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980). Notice-and-comment rulemaking facilitates public input into agency decision-making, as well as greater transparency and clarity on the part of the agency—and in this way provides an important check against unbridled administrative power. Because the administration of Medicare implicates the health of millions of Americans, fulsome opportunities for public input are essential.

ARGUMENT

I. NOTICE-AND-COMMENT RULEMAKING PROMOTES FAIRNESS AND PUBLIC PARTICIPATION IN REGULATORY OVERSIGHT.

A. Prospective Rulemaking Through Notice-And-Comment Promotes Consistency And Clarity.

The benefits of prospective, notice-and-comment rulemaking are well recognized. The promulgation of prospective rules through notice-and-comment rulemaking "ensures fairness to affected parties" in two important ways. *Sprint Corp.*, 315 F.3d at 373 (quoting *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983)). First, prospective rulemaking gives parties advance notice so they can conform their conduct according to settled expectations. "Elementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct

accordingly." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994). The notice-and-comment process promotes such fairness by "informing affected parties and affording them a reasonable time to adjust to the new regulation." *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).

The comment procedures also promote another "essential component" of fairness: They give affected parties "the opportunity to be heard" regarding the rules they will be subject to. *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547 (citing *Nat'l Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 949 (D.C. Cir. 1982)). To the extent agency action threatens the rights and interests of a regulated party, basic fairness dictates that the party "be given a chance to present their case to the [agency] before [it] acts." *Schweiker*, 690 F.2d at 949 (describing this as "the fairness element" of the Administrative Procedure Act's notice-and-comment procedures).

For these reasons, prospective rulemaking via notice-and-comment "is generally a 'better, fairer, and more effective' method of implementing a new industry-wide policy than is the uneven application of conditions in isolated" adjudications. *Cmty. Television of S. Cal. v. Gottfried*, 459 U.S. 498, 511 (1983). "Making policy through adjudication can lead to inconsistent outcomes and frustrates expectations when policy changes retroactively. Making policy through rulemaking is much more likely to result in standards that apply prospectively, providing clear notice of the law's requirements to all concerned." Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 Harv. L. Rev. 467, 546 (2002); *see also* Kenneth Culp Davis, *Discretionary Justice* 66 (Univ. of Ill. Press 1971) (1969) (due to the "unfair[ness]" of retroactive

application, "prospective rules often should be preferred to retroactive law-making through adjudication").

B. Notice-And-Comment Rulemaking Permits Democratic Participation And Oversight Of The Agency.

Prospective rulemaking also achieves the important purpose of giving affected parties and the public the opportunity to weigh in on important policy debates. *Schweiker*, 690 F.2d at 950. Congress enacted the notice-and-comment procedures in the Administrative Procedure Act (APA) for precisely that reason: "to give the public an opportunity to participate in the rule-making process." *Texaco, Inc. v. Fed. Power Comm'n*, 412 F.2d 740, 744 (3d Cir. 1969); *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1157–58 (noting the "congressionally-mandated policy of affording public participation that is embodied in [the APA's notice-and-comment procedures]"). Congress believed that, "due to the unrepresentative nature of an administrative agency, 'public participation . . . in the rulemaking process is essential in order to permit administrative agencies to inform themselves, and to afford safeguards to private interests.'" *Batterton*, 648 F.2d at 703 n.47 (quoting S. Doc. No. 248, 79th Cong., 2d Sess. 19–20 (1946)).

Public participation in rulemaking is essential for several reasons. First and foremost, "public participation assures that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions." *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978). Specifically, "[n]otice and comment gives interested parties an opportunity to participate through the submission of data, views and

arguments." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 12–13 (D.D.C. 2004). This exchange of information "enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Texaco*, 412 F.2d at 744.

Second, and relatedly, public rulemaking "increase[s] the likelihood of administrative responsiveness to the needs and concerns of those affected." *Guardian*, 589 F.2d at 662. After all, regulated entities and stakeholders are particularly likely to have "valuable information" regarding a proposed rule. *Schweiker*, 690 F.2d at 950 (noting that home health agencies would likely have valuable information and insight regarding a proposed rule because they "had been dealing with the various intermediaries and working with the Medicare system for years"). By requiring the agency to consider their viewpoints, public rulemaking ensures that agencies do not promulgate rules that "substantially affect private parties and resolve important issues without the beneficial input that those parties could provide." *Id.* And even if regulated entities and stakeholders ultimately disagree with the final rule, notice-and-comment procedures "tend[] to promote acquiescence in the result." *Guardian*, 589 F.2d at 662.

Of course, "[t]he more expansive the regulatory reach of the[] rule[], . . . the greater the necessity for public comment." *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1156. And public rulemaking is especially important where, as here, "one can expect real interest from the public in the content of the proposed regulation." *Levesque v. Block*, 723 F.2d 175, 185 (1st Cir. 1983) (holding that notice-and-comment was required where "plaintiffs show[ed] interest in the content of the regulation, [and] many commentators

participated in the final rulemaking when given an opportunity"). *See also, e.g., Nat'l Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (holding that agency was required to use public rulemaking procedures because the agency's rule had extensive regulatory reach and the legislative history suggested that the public would be interested in the rule). Given the indisputable importance of the Medicare program, there can be no doubt that the public will want a say in how the nation's healthcare budget is directed. *See* Robert Pearl, *Healthcare is the No. 1 Issue for Voters; A New Poll Reveals Which Healthcare Issue Matters Most*, Forbes (Aug. 13, 2018, 7:53 AM), https://www.forbes.com/sites/robertpearl/2018/08/13/midterms/#12aa2ff73667.

II. THE USE OF NOTICE-AND-COMMENT RULEMAKING IMPROVES REGULATORY OUTCOMES.

These well-recognized benefits of notice-and-comment rulemaking processes apply with particular force in the context of Medicare reimbursement regulations. Prospective rulemaking via notice-and-comment is critical where, as here, the affected parties face the risk of civil penalties and even criminal liability if they fail to comply with an agency's rules. Moreover, in light of the signal importance of healthcare and Medicare coverage to the American economy, preserving opportunities for public oversight of the Medicare program is critical.

With its single-minded focus on the burdens of notice-and-comment rulemaking, HHS all but ignores the other side—both the costs that are imposed on Medicare providers and beneficiaries when Medicare policy is conducted without opportunity for public comment, and the important benefits that accrue

when the public participates in the development of regulatory policy.

A. When HHS Has Failed To Use Notice-And-Comment Rulemaking, Unfairness And Confusion Have Resulted.

To demonstrate the real-world stakes of HHS's regulatory practices, *amici* describe below two examples where HHS's failure to engage in notice-and-comment rulemaking, and its failure to provide clear and generally applicable rules, have led to inconsistency and unfairness for providers and beneficiaries.

1. National Coverage Determinations Versus Local Contractor Actions.

A. The Medicare Act provides that no Medicare payment may be made to a physician under Medicare Part B if items or services are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Thus, in order to obtain Medicare reimbursement, providers must make certifications relating to the services they have provided to patients—including a certification of medical necessity. *See* 42 U.S.C. § 1395f(a)(2)-(3) (Medicare payment "may be made only . . . if," *inter alia*, "a physician certifies that such services are required to be given"). In practical terms, when submitting Form CMS-1500 for payment under the Medicare program, a physician must certify via signature that, among other things, "the services on this form were medically necessary," and "I [the

provider] have familiarized myself with all applicable laws, regulations, and program instructions."[5]

HHS decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The former course involves a National Coverage Determination (NCD). Through NCDs, HHS announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). As relevant here, NCDs are "nationwide, prospective, population-based policies that apply to clinical subsets or classes of Medicare beneficiaries and describe the clinical circumstances and settings under which particular services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. 54,534, 54,535 (Aug. 22, 2002). Under the current statute, HHS is required to use notice-and-comment procedures to promulgate NCDs—allowing at least 30 days for public comment before a final decision is made. 42 U.S.C. § 1395y(l)(3); *see also* 78 Fed. Reg. 48,164 (Aug. 7, 2013). NCDs are binding and have the force of law. *See* 42 C.F.R. § 405.1060.[6]

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[5] The form can be seen at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. Ctrs. for Medicare & Medicaid Servs., OMB-0938-1197, *Health Insurance Claim Form*, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last revised Feb. 1, 2012).

[6] As respondents explain, at the time that the statute at issue here, 42 U.S.C. § 1395hh(a)(2), was enacted, NCDs were adopted without notice-and-comment—and NCDs were explicitly carved out of that section's notice-and-comment requirement. Br. for Resp'ts at 39-40. Given the importance of NCDs to provider reimbursement, however, Congress later adopted a separate notice-and-comment requirement for NCDs. *See* 42 U.S.C. § 1395y(l)(3).

In the absence of an NCD, whether services are reasonable and necessary is determined by local Medicare Administrative Contractors—*i.e.*, private entities with which HHS contracts to administer Medicare. A contractor may issue a Local Coverage Determination (LCD), which announces "whether or not a particular item or service is covered" by that particular contractor. 42 U.S.C. § 1395ff(f)(2)(B). By statute, LCDs are subject to a form of notice-and-comment, in that they must be published on the contractor's website for a minimum of 45 days before they become effective. 42 U.S.C. § 1395y(l)(5)(D). Otherwise, however, LCDs are different from NCDs because (a) they do not apply at all beyond the individual contractor that has adopted them, and (b) they are not binding on the agency. *See* 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003) (administrative law judge reviewing a contractor's claim denial "may consider, but [is] not bound by" the LCD in determining whether care is reasonable and necessary). If no NCD or LCD applies, contractors may also "make individual claim determinations, even in the absence of [a national or local coverage determination], . . . [B]ased on the individual's particular factual situation." *Id.*

B. In practice, LCDs are neither generally applicable regulations nor individual adjudications. Instead, they operate as uniform coverage decisions by the private insurers that serve as Medicare contractors. LCDs outline whether a particular private insurer will consent to allow Medicare reimbursement for treatments based on a collection of symptoms and indications taken out of the context of the individual patient's needs.

The reliance on these informal, regional, privately determined policies gives rise to adverse effects for

both physicians and patients. For one thing, it creates patchwork and inconsistent coverage that varies from region to region for Medicare beneficiaries. As the HHS Inspector General wrote, the use of LCDs means that Medicare "beneficiaries' access to items and services can depend on geography as much as their clinical indications." Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-01-11-00500, *Local Coverage Determinations Create Inconsistency in Medicare Coverage* 9 (2014), https://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf. "[B]eneficiaries in some States did not have access to items and services that had significant use among beneficiaries in other States," and "the likelihood that beneficiaries' items and services had coverage restrictions placed on them by LCDs varied widely by State." *Id.* at 9, 11. Moreover, these problems of inconsistency were not isolated to a handful of discrete procedures: to the contrary, "[o]ut of the 540 clinical topics addressed by LCDs, none were addressed by an LCD in every State—meaning that *every clinical topic was addressed in some States but not others.*" *Id.* at 11 (emphasis added).

By way of example, in 2008, Medicare patients with prostate cancer were eligible for a surgical treatment called CyberKnife if they lived in one of 33 states, but not if they lived in the other 17. *See, e.g.*, Stephanie Saul, *Geography Has Role in Medicare Cancer Coverage*, N.Y. Times (Dec. 16, 2008), https://www.nytimes.com/2008/12/17/health/policy/17knife.html. Thus, "Medicare will pay for a man's CyberKnife treatments in New Hampshire, but not across the border in Vermont"; "'[y]ou can live on one side of the street and get a procedure, but on the other side of the street you can't.'" *Id.* CyberKnife is in this way

"emblematic of the inconsistent way that the federal Medicare budget . . . is spent, region to region." *Id.*

Another adverse effect of reliance on LCDs is that—even though LCDs are deemed by HHS to be non-binding—physicians face grave risks by departing from LCDs. Recently, the government and/or *qui tam* relators have brought False Claims Act challenges against physicians arguing that billing Medicare for a service that is not medically necessary amounts to a fraudulent claim, and therefore subjects the physician to civil and/or criminal liability under the act. *See United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018); *United States v. Persaud*, 866 F.3d 371 (6th Cir. 2017); *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018). Some courts have treated LCDs as legally binding for purposes of liability under the False Claims Act: where a physician's treatment deviated from the LCD, the physician was found to have fraudulently billed Medicare. *U.S. ex rel. Ryan v. Lederman*, No. 04-2483, 2014 WL 1910096, at *4 (E.D.N.Y. May 13, 2014); *U.S. ex rel. Youn v. Sklar*, 273 F. Supp. 3d 889, 896 (N.D. Ill. 2017).

The case *United States ex rel. Ryan v. Lederman* is illustrative. The defendant, Dr. Lederman, performed radiation treatment and stereotactic radiosurgery to treat cancer. 2014 WL 1910096, at *1. The local contractor for his jurisdiction issued two LCDs (then called LMRPs) that defined "stereotactic radiosurgery" and listed eight conditions that would trigger coverage. *Id.* at *2. One of the LCDs noted that "treatment of below the neck of diseases such as lung carcinoma with stereotactic radiosurgery [was] considered investigational at [that] time." *Id.* The government alleged that Dr. Lederman had submitted claims for reimbursement for below-the-neck stereotactic radiosurgery claims—and argued that

because the local contractor's LCDs excluded below-the-neck stereotactic radiosurgery from coverage, Dr. Lederman's claims for reimbursement for such procedures were false as a matter of law.

In his defense, Dr. Lederman argued that HHS's own regulations establish that LCDs are not controlling and provide only "guidance" on procedure coverage. *Id.* at *4. The court rejected Dr. Lederman's argument, stating: "I do not believe . . . that LCDs are advisory or not authoritative. . . . (Put another way, 'guidance' can be mandatory.)" *Id.* In a confusing twist, the government offered another HHS guidance document that described the general role of LCDs in support of its view that LCDs are binding for reimbursement determinations. *Id.* at *4-5. (citing *Medicare Program, Procedures for Making National Coverage Determinations*, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999)). Accepting the government's argument, the court concluded that "[t]he passage [cited by the government] makes clear that LCDs are mandatory for areas they cover." *Id.* at *5.

C. This example underscores the need for clarity in the form of generally applicable notice-and-comment rulemaking where the government makes consequential policy determinations governing physicians. The issuance of an NCD provides unambiguous, consistent authority on which physicians and patients can rely. Moreover, proceeding through centralized notice-and-comment rulemaking facilitates the participation of groups that have useful insights to offer. Notice-and-comment rulemaking on national coverage for CyberKnife, for example, would allow the AMA, the American Urological Association, the Mayo Clinic, the private insurance industry, and the general public to weigh in

on whether this is an appropriate use of Medicare funds.

Without such authoritative regulatory action, physicians struggle to know when they are providing treatment in compliance with Medicare policies versus when they could be subject to a criminal charge. And coverage determinations lose the benefit of commentary from interested parties who can offer evidence of clinical effectiveness. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., *Local Coverage Determinations, supra*, at 13 ("the State-by-State differences in coverage created by LCDs are contrary to the growing practice of evidence-based medicine"). This creates an unfair system for physicians and regulatory scheme that lacks public input.

2. The Two-Midnight Rule.

A. The definition of "inpatient" services offers another example where generally applicable rulemaking through notice-and-comment would provide much-needed clarity for providers and patients. The Medicare Act provides for payment of the costs of "inpatient" hospital stays under Medicare Part A. *See* 42 U.S.C. §§ 1395d, 1395ww. By contrast, outpatient treatment is covered under Medicare Part B. *See* 42 U.S.C. § 1395k. The difference is financially significant for patients. Among other things, if care is billed under Part A, Medicare pays the total qualifying cost after a patient deductible. For care under Part B, Medicare generally pays 80 percent of costs and the patient is responsible for the remaining 20 percent. 42 U.S.C. §§ 1395e, 1395l.

However, what qualifies as "inpatient" versus outpatient care is ambiguous. The term "inpatient" is not defined in the statute. Nor, for many years, was

"inpatient" defined by regulation; instead, HHS issued a variety of guidance documents purporting to clarify which patients qualify to be billed under Part A for inpatient hospital services as opposed to Part B for outpatient service. In 2013, HHS at last promulgated via notice-and-comment a rule addressing "inpatient" care: a patient's hospital stay is to be reimbursed as "inpatient" care under Part A if the patient is "formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner" 42 C.F.R. § 412.3(a). The regulation goes on to explain the circumstances in which a physician should admit a patient for inpatient care: "an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights." *Id.* § 412.3(d)(1). This has come to be known as the "two-midnight rule."

B. Unfortunately, the two-midnight rule created a host of questions and confusion. Many hospital stays that extend beyond two midnights are not reimbursed as "inpatient" admissions. The HHS Inspector General determined that in Fiscal Year 2014, nearly 750,000 hospital stays for Medicare beneficiaries that extended beyond two midnights were billed as outpatient stays. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-02-15-00020, *Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy* 12 (2016), https://oig.hhs.gov/oei/reports/oei-02-15-00020.pdf. As the Inspector General explained, this appeared to be the result of confusion generated by the two-midnight rule and HHS's other policies:

> A large number of long outpatient stays is somewhat unexpected because these stays likely met the 2-midnight policy's expected-length-of-stay requirement for inpatient admission, and

> providers have a financial incentive to admit beneficiaries as inpatients when possible. That providers did not admit these beneficiaries may indicate that other factors caused them to continue to bill for a large number of long outpatient stays. These factors may include an inability to safely discharge beneficiaries, delays in care, or confusion about the 2-midnight policy.

Id.

As the Inspector General also explained, the high number of long outpatient stays is troubling because it imposes significant financial burdens on patients. Beneficiaries in more than 350,000 outpatient stays incurred costs in excess of the inpatient deductible—*i.e.*, the most they would have paid if they had been deemed inpatients—because care billed under Medicare Part B is billed at "20 percent of Medicare's rate for each service, and there is no cap on the total amount [these beneficiaries] can be responsible for paying." *Id.* at 13. Beneficiaries in outpatient stays also incurred charges for self-administered drugs that would be covered for an inpatient stay. *Id.* And many beneficiaries in outpatient stays "fac[ed] substantial charges after they le[ft] the hospital," because Medicare pays for a skilled nursing facility (such as a rehabilitation facility) "only if a beneficiary had a hospital stay that included at least 3 nights as an inpatient." *Id.*

In short, the lack of regulatory clarity surrounding the two-midnight rule has given rise to "one of the brutal truths of Medicare policy: Patients can be hospitalized for days, can undergo exams and tests, can receive drugs—without ever officially being admitted to the hospital," which means they "can face higher payments for drugs and coinsurance, but the big-ticket item is nursing home care." Paula Span,

Under 'Observation,' Some Hospital Patients Face Big Bills, N.Y. Times (Sept. 1, 2017), https://www.nytimes.com/2017/09/01/health/medicare-observation-hospitals.html; *see also* Elliot Raphaelson, *Inpatient vs. Observation Status: The Difference Can Be Costly*, Chi. Trib. (Nov. 21, 2018, 4:20 PM), https://www.chicagotribune.com/business/sns-201811211100--tms--savingsgctnzy-a20181121-20181121-story.html ("Unfortunately, Medicare policies and hospital policies in this area are ambiguous. . . . The current practices don't protect patients at all."); *Barrows v. Burwell*, 777 F.3d 106 (2d Cir. 2015) (putative class action on behalf of Medicare beneficiaries, challenging Medicare reimbursement practices for hospital stays). Patients face financial risks that are outside their control. And physicians face risks as well, for if they "incorrectly" bill for inpatient services, they can be subject to False Claims Act liability.

C. Despite the well-recognized problems with the two-midnight rule, HHS has not engaged in any further notice-and-comment regulation on the topic of "inpatient" status since the adoption of its 2013 rule. Although the agency allowed for public comment then, it has not engaged in a fulsome notice-and-comment process since that time to allow stakeholders an opportunity to identify and propose solutions for the unintended consequences and remaining problems following the agency's regulation. Instead of addressing inpatient admissions through notice-and-comment rulemaking, HHS has limited its response to informal guidance documents and FAQ answers.[7]

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[7] *See* 83 Fed. Reg. 41,144, 41,506-10 (Aug. 17, 2018); Ctrs. for Medicare & Medicaid Servs., MM10080, *Clarifying Medical Review of Hospital Claims for Part A Payment* (May 16, 2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf;

Moreover, other HHS policies—including increasing scrutiny of inpatient admissions through audits, as well as penalties for readmissions, which apply only to patients who were originally admitted as inpatients—have favored cost savings over objective patient care, and thereby exacerbated this problem. *See* Zhanlian Feng et al., *Sharp Rise in Medicare Enrollees Being Held in Hospitals for Observation Raises Concerns about Causes and Consequences*, 31 Health Aff. 1251, 1256-57 (2012). In light of HHS's failure to provide a clear resolution of the issue through notice-and-comment rulemaking, the AMA has pledged to "work with third party payers to establish a uniform definition of 'observation care,'" based on patient-focused factors. *See* Council on Med. Serv., Am. Med. Ass'n, *Defining "Observation Care" H-160.944* (2014), https://policysearch.ama-assn.org/policyfinder/detail/Defining%20Observation%20Care%20H-160.944?uri=%2FAMADoc%2FHOD.xml-0-758.xml (last visited Dec. 18, 2018).

In order to avoid further financial burdens for beneficiaries and risk for providers, a clear rule—adopted with notice and opportunity for public comment from both beneficiaries and providers—is called for. To be sure, notice-and-comment was undertaken prior to the 2013 rule, but that rule did not resolve the issue of inpatient admissions. Further opportunity for comment by stakeholders and the public—informed by the experiences of providers and beneficiaries in recent years—would make for stronger

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80 Fed. Reg. 70,298, 70,305 (Nov. 13, 2015); Ctrs. for Medicare & Medicaid Servs., *Frequently Asked Questions: 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or After October 1, 2013*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf (last visited Dec. 18, 2018).

regulatory policy. By engaging the public, HHS could benefit from the input of physicians and hospitals as to the pitfalls of the two-midnight rule and HHS's subsequent guidance, and obtain practical suggestions for a better course. Moreover, Medicare beneficiaries could bring their experiences to bear, so that the agency would have a better-informed approach going forward.

B. By Contrast, HHS's Use Of Notice-And-Comment Rulemaking Has Improved The Quality And Administrability Of Regulations.

On the other hand, where HHS has used formal, notice-and-comment rulemaking, public participation has led to better outcomes. Indeed, it can be no surprise that more information leads to better rulemaking. *See Sprint*, 315 F.3d at 373 ("[T]he notice requirement improves the quality of agency rulemaking by exposing regulations to diverse public comment.") (quoting *Small Refiner*, 705 F.2d at 547).

This is well exemplified by the important role the AMA plays in shaping Medicare reimbursement rules each year. Each summer, HHS publishes a proposed rule regarding the Medicare fee schedule for the following calendar year. *See, e.g., Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule*, 83 Fed. Reg. 35,704 (July 27, 2018). Among other things, the proposed rule revises payment policies and amounts for all physicians' services paid under the Medicare Physician Fee Schedule (PFS). *Id.* at 35,704-05. The goal of the proposed rule is to "ensure that . . . payment systems are updated to reflect changes in medical practice and the relative value of services." *Id.* at 35,705.

After publication, the AMA analyzes the proposed rule and solicits feedback from specialty and regional medical societies throughout the nation. *See, e.g.*, Andis Robeznieks, *Less Documentation, E/M Pay Changes Proposed in 2019 Fee Schedule*, Am. Med. Ass'n (Aug. 2, 2018), https://www.ama-assn.org/practice-management/medicare/less-documentation-em-pay-changes-proposed-2019-fee-schedule. Based on that feedback, the AMA submits a substantial set of comments, designed to identify unintended consequences, explain where pricing is inconsistent with physician experience, and also to laud positive policy changes. *See, e.g.*, Letter from James L. Madara, Am. Med. Ass'n, to Hon. Seema Verma, Administrator, Ctrs. for Medicare & Medicaid Servs. (Sept. 10, 2018), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-9-10-2019-PFS-QPP-Comment-Letter-FINAL-2.pdf.

When drafting the final rule, HHS considers and incorporates the AMA's comments. *See, e.g.*, *Summary: 2019 Medicare Physician Fee Schedule and Quality Payment Program Final Rule* 2–3, Am. Med. Ass'n (2018), https://www.ama-assn.org/system/files/2018-11/pfs-qpp-final-rule-sum11-8.pdf (noting that CMS did not adopt certain aspects of the proposed rule that the AMA opposed). Sometimes, HHS even delays implementation of a proposed policy to give the AMA the opportunity to experiment or conduct further research and share its findings with the HHS. *See, e.g.*, *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule*, 83 Fed. Reg. 59,452, 59,638 (Nov. 23, 2018) (noting that a two-year delay in implementation for certain coding and payment related-changes would "provide the opportunity for

[CMS] to respond to the work done by the AMA" in that area).

This process permits efficient and centralized dialog between HHS, major stakeholders, and the public—and is accomplished within a matter of months. *See* Br. in Opp'n 35-36 & Addendum. Through this back and forth between the agency, the AMA, and in turn the regional and specialty groups, the final rules are better informed and more effective. Moreover, the public has a fulsome opportunity to weigh in on how Medicare's large and growing budget is directed. More rather than less formal rulemaking for Medicare is warranted.

CONCLUSION

Amici share respondents' concern with HHS's attempt to skip notice-and-comment rulemaking "when altering a substantive legal standard that reduces payments to hospitals—to the tune of billions of dollars." Br. for Resp'ts 2-3. In weighing HHS's stated concerns with inflexibility in its regulatory practices, the Court should also bear in mind the important benefits of generally applicable rules adopted through the notice-and-comment process.

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